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THE DOW CHEMICAL COMPANY

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**ATTENTION: 8(D) HEALTH AND SAFETY REPORTING RULE
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Dear Sir or Madam:

As required by 40 CFR amended, we herewith submit a copy of the
following recently completed health and safety study.

Propylene Dichloride: Oral Teratology Probe Study in New
Zealand White Rabbits

<u>Chemical Name</u>	<u>CAS Number</u>
Propylene Dichloride	78-87-5

The Dow report identification number, **D0002752**, has been marked at the top of the title page of the report. Please refer to this Dow identification number in any communication regarding this study. **The enclosed report does not contain Dow Confidential Business Information.**

Very truly yours,

Robert L. Hagerman

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enclosure

D002752

Study Title

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY
IN NEW ZEALAND WHITE RABBITS

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Final Report

September 8, 1988

Performing Laboratory

Mammalian and Environmental Toxicology Research Laboratory
Health and Environmental Sciences
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Midland, Michigan 48674

Laboratory Project Study ID

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PAGE 2

Page Two is reserved for the inclusion of a Statement of Data Confidentiality Claims as required by the United States Environmental Protection Agency (EPA) under the provisions of PR NOTICE 86-5 issued July 29, 1986.

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

To the best of my knowledge and belief the study described in this report was conducted in compliance with the following Good Laboratory Practice Standards:

United States Environmental Protection Agency,
Title 40 Code of Federal Regulations Part 792,
Federal Register, 29 November 1983

Japan Ministry of Agriculture, Forestry and Fisheries,
59 Nohsan, Notification No. 3850,
Agricultural Production Bureau,
10 August 1984

Organization for Economic Co-Operation and Development
ISBN 92-64-12367-9, Paris 1982

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QUALITY ASSURANCE STATEMENT

**STUDY TITLE: PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE
STUDY IN NEW ZEALAND WHITE RABBITS**

This study was examined for conformance with Good Laboratory Practices as published by the U.S. Environmental Protection Agency, and the Food and Drug Administration. The final report was determined to be an accurate reflection of the data obtained. The dates of Quality Assurance activities on this study are listed below.

Study Start Date: 2-4-88

Date of Final Report: 9-8-88

TYPE OF AUDIT:	DATE OF AUDIT:	DATE FINDINGS REPORTED TO (STUDY DIRECTOR/MANAGEMENT)
Preliminary protocol	2-1-88	2-1-88
Final protocol	2-9-88	2-9-88
Protocol, study conduct,		
Draft report	5-19-88	5-26-88

ARCHIVING: Raw Data and a copy of the final report are filed in the testing facility archives.

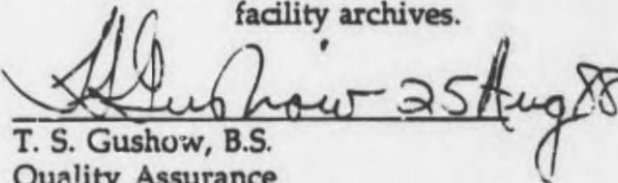

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SUMMARY

Propylene dichloride (1,2-dichloropropane, PDC) was tested to determine appropriate dose levels for a gavage teratology study. Groups of seven inseminated New Zealand White rabbits were administered PDC by oral gavage on gestation days 7 to 19 at dose levels of 0, 25, 100, or 250 mg/kg body weight/day. Treatment-related anemia was observed among pregnant rabbits in both the 100 and the 250 mg/kg/day dose groups, as evidenced by decreased hematocrit, hemoglobin concentration, and red blood cell count, as well as increases in reticulocyte count and morphologic changes in red blood cells consistent with regeneration. Though there were no statistically significant differences in organ weights among the treated groups, both absolute and relative liver, kidney and spleen weights were elevated among rabbits given 250 mg PDC/kg/day, and there were suggestions of increases in liver and/or kidney weights among animals given 25 or 100 mg/kg/day. Among rabbits administered 250 mg/kg/day, there was an apparent treatment-related increase in the resorption rate, though this difference was not statistically identified. Based on these results, dose levels of 0, 15, 50, and 150 mg/kg/day were selected for the definitive teratology study in New Zealand White rabbits.

INTRODUCTION

Propylene dichloride (1,2-dichloropropane, PDC) is used as a solvent and a chemical intermediate. The current TLV as set by the American Conference of Governmental Industrial Hygienists is 75 ppm (ACGIH, 1986). An oral LD50 for PDC of 1.9 g/kg in Wistar rats has been reported (Smyth et al., 1969) as well as an 8-hr LC50 of 3000 ppm (Pozzani et al., 1959).

In a range-finding study (Kirk et al., 1988), female New Zealand White rabbits were administered PDC in corn oil by gavage at dose levels of 0, 250, 500 or 1000 mg/kg/day for 13 days. Repeated exposure to 500 mg/kg/day or above produced general signs of lethargy and ataxia and was lethal to both rabbits/dose group within 3-5 days of dosing. These rabbits also exhibited centrilobular necrosis of the liver. Repeated dosing of rabbits at 250 mg/kg/day produced decreased weight gain, with one of two rabbits dying after 9 doses. The remaining rabbit administered 250 mg/kg/day survived until scheduled necropsy.

The purpose of this probe study was to establish dose levels for a subsequent teratology study in rabbits via the oral route as called for in final EPA TSCA Section 4 Test Rule requirements for PDC (EPA, 1987). This study was conducted to meet the requirements of Good Laboratory Practice for Non-Clinical Studies (FDA, 1978), the Environmental Protection Agency (EPA): TSCA Good Laboratory Practice Procedures (EPA, 1983), the EPA: TSCA Test Guidelines (EPA, 1985) and the Standard Operating Procedures of The Dow Chemical Company Mammalian and Environmental Toxicology Research Laboratory.

MATERIALS AND METHODS

Test Material. The test material was obtained from the Texas Division, Dow Chemical USA, Freeport, TX and was identified as Lot No. TB871112.

Analysis of the test material by capillary gas chromatography indicated a purity of 99.9% (Gerhart and Schlesinger, 1988).

Test Animals. Stock supplies of male and female New Zealand White rabbits were obtained from Hazleton-Dutchland, Inc. (Denver, PA). The New Zealand White rabbit was chosen as the test species based on its general acceptance for developmental toxicity testing, the availability of a reliable commercial supplier, and the availability of historical control data. Upon receipt in the laboratory¹ all animals were examined for health status by a veterinarian and acclimated to laboratory conditions for at least two weeks prior to breeding in a room designed to maintain environmental conditions with respect to temperature, relative humidity, airflow and lighting conditions, and regulated for the species on test. Female rabbits (approximately 3.5-4.5 kg) were injected via the marginal ear vein with 50 I.U. of chorionic gonadotropin² (CG) 3 weeks prior to the date of insemination in order to synchronize estrous. Twenty-eight female rabbits were artificially inseminated (Gibson et al., 1966), with the day of insemination considered Day 0 of gestation, and injected again with CG to induce ovulation. Randomization of inseminated animals based on body weights was performed using a computer-generated procedure. Animals placed on study were housed individually in wire bottom cages and uniquely identified using numbered metal ear tags. Animals were maintained on 4 oz/day of Certified Laboratory Rabbit Chow No. 5322 (Ralston Purina Company, St. Louis, MO) prior to the start of the study. Feed allocations were then increased to 8 oz/day during the study to allow for the increased nutritional demands during pregnancy. Municipal tap water was available ad libitum. Water and feed analyses were performed according to the Standard Operating Procedures of The Dow Chemical Company Mammalian and Environmental Toxicology Research Laboratory.

¹Fully accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC).

²W. A. Butler Company, Columbus, OH.

Compound Preparation and Administration. PDC was administered in corn oil at dose levels of 0 (vehicle control), 25, 100 mg/kg/day. Oral gavage was selected as the route of exposure because it was required in the Final EFC Test rule, and corn oil was selected as the vehicle because of the limited solubility of PDC in water. Test solutions were prepared once over the course of the study such that a dose volume of 1.0 ml/kg/day yielded the appropriate dose. Analyses of the dosing solutions were performed at the start of the study to verify PDC concentrations. Kropscott (1988a) has demonstrated the stability of propylene dichloride (PDC) in corn oil solutions for up to 65 days after preparation using flame ionization gas chromatography:

PDC STABILITY IN CORN OIL

Sample Day ^a	Concentration		Concentration	
	<u>Targeted^b</u>	<u>Observed^b</u>	<u>Targeted^b</u>	<u>Observed^b</u>
0	5.0	5.1 ± 0.2	500	478 ± 4
31	5.0	5.1 ± 0.0	500	490 ± 6
65	5.0	5.7 ± 0.4	500	530 ± 8

^aSelected time periods (in days) over which stability of two different PDC/corn oil solutions was determined.

^bmg PDC/ml corn oil.

Mixing homogeneity was verified by collecting 6 different aliquots from two different PDC/corn oil solutions (Kropscott 1988b):

PDC HOMOGENEITY IN CORN OIL

Aliquot Number	Concentration		Concentration	
	<u>Targeted^a</u>	<u>Observed^{a,b}</u>	<u>Targeted^a</u>	<u>Observed^{a,b}</u>
1	5.0	5.22	500	482
2	5.0	5.26	500	482
3	5.0	4.91	500	475
4	5.0	5.25	500	480
5	5.0	5.39	500	476
6	5.0	5.21	500	471

^amg PDC/ml corn oil.

^bSamples analyzed using flame ionization gas chromatography.

Experimental Design. Groups of seven inseminated rabbits were administered PDC in corn oil by gavage on Days 7 through 19 of gestation at dose levels of 0, 25, 100 or 250 mg/kg/day. Body weights were recorded on Day 0, daily during the dosing period, and on Day 20 of gestation. Dose volumes were adjusted daily based on body weight. All animals were observed daily during the course of the study for signs of toxicity due to the test material. Any animal which died was submitted for a complete necropsy examination. Statistical analyses of body weights and weight gains were performed using data collected on Days 0, 7, 10, 13, 16, 19, and 20 of gestation.

Necropsy. On Day 20 of gestation, all animals which survived the dosing regimen were sacrificed by decapitation following CO₂ asphyxiation and clamping of the trachea. Immediately after decapitation, the eyes were examined in situ by a glass slide technique. A detailed necropsy examination was performed by a veterinary pathologist. A detailed examination of the uterus for implantations and resorptions was performed by personnel from the Reproductive Toxicology Group. Hematologic determinations of hematocrit, hemoglobin concentration, erythrocyte count, total leukocyte count, erythrocyte indices (MCV, MCH, MCHC) and platelet count were conducted on blood samples collected on day 19 of gestation. Stained blood

smears were prepared from all rabbits and evaluated for erythrocyte morphology. Blood smears were also prepared and evaluated for reticulocyte count. Serum samples were collected at the time of necropsy and frozen; however, serology was not conducted. Smears of sternal bone marrow were prepared, but were not evaluated.

Maternal liver, kidney and spleen weights, the number of corpora lutea, and the number and position of implantations and resorptions were recorded at the time of necropsy. The uteri of apparently non-pregnant animals were stained with a 10% solution of sodium sulfide (Kopf et al., 1964) and examined for evidence of early resorptions. Sections of maternal liver, kidneys, spleen, and bone marrow (sternum) were preserved in neutral, phosphate-buffered 10% formalin but were not examined histologically.

Statistical Evaluation. Maternal body weights and weight gain, hematology (except for those parameters excluded from analysis) and absolute and relative organ weights of pregnant rabbits were evaluated by Bartlett's test for equality of variances followed by a parametric analysis of variance (ANOVA). If the ANOVA was significant, analysis by Dunnett's test was performed. Statistical evaluation of the frequency of pre-implantation loss and resorptions among litters and the fetal population was performed using a censored Wilcoxon test with Bonferroni's correction. The number of corpora lutea and implantations and litter size were evaluated using a nonparametric ANOVA followed by the Wilcoxon Rank-Sum test with Bonferroni's correction. Pregnancy rate was analyzed using the Fisher exact probability test. Statistical outliers were identified by a sequential outlier test, but were not excluded from analyses.

The nominal alpha levels used were as follows:

Bartlett's Test of Variance	$\alpha=0.01$
(Winer, 1971)	

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Parametric ANOVA (Steel and Torrie, 1960)	$\alpha=0.10$
Nonparametric ANOVA (Hollander and Wolfe, 1973)	$\alpha=0.10$
Dunnett's Test (Winer, 1971)	$\alpha=0.05$, two-sided
Wilcoxon Rank-Sum Test (Hollander and Wolfe, 1973) with Bonferroni's correction (Miller, 1966)	$\alpha=0.05$, two-sided,
Fisher's Test (Siegel, 1956)	$\alpha=0.05$, one-sided
Censored Wilcoxon Test (Haseman and Hoel, 1974)	$\alpha=0.05$, one-sided
Outlier Test (Grubbs, 1969)	$\alpha=0.02$, two-sided

Because numerous measurements were statistically compared in the same group of animals, the overall false positive rate (Type I errors) was expected to be much greater than the cited alpha levels would suggest. Therefore, the final interpretation of the numerical data considered the statistical analyses along with other factors such as dose-response relationships and whether the results were significant in light of other biologic and pathologic findings.

RESULTS AND DISCUSSION

Test Material

Analyses of the dosing solutions used in this study are presented in Table 1. The analyses indicated that the concentrations of the test material in the solutions ranged from 95% to 98% of the targeted concentrations (Kropscott, 1988c).

Observations

A summary of clinical observations for test rabbits is presented in Table 2. Two rabbits at the 250 mg/kg/day dose level were found dead on gestation days 15 and 18, respectively. No deaths were observed at any other dose level tested. A similar incidence of mortality at the 250 mg/kg/day dose level was observed in the previously cited range-finding study (Kirk et al., 1988). There were no statistically significant effects on body weights (Table 3), body weight gains (Table 4), or absolute and relative organ weights (Table 5) among treated rabbits when compared with controls. However, both absolute and relative liver, kidney and spleen weights were elevated among rabbits given 250 mg/kg/day, and there were suggestions of increases in liver and/or kidney weights among animals given 25 or 100 mg/kg/day. However, due to the small group sizes, and the large fluctuations in organ weights among pregnant animals, no definitive interpretation as to possible organ weight effects could be made.

Pathology

Gross pathologic observations made at the time of necropsy are summarized in Tables 6 and 7. The causes of death of the two rabbits that died at the 250 mg/kg/day dose level were not determined, but there were no specific signs of target organ toxicity. Changes noted at necropsy were consistent with anorexia and debilitation and included decreased ingesta, gastric erosions and/or ulcers, pulmonary congestion and edema, and pale liver and kidneys (Table 6). There were no gross pathologic observations attributed to gavage with PDC in rabbits surviving until scheduled necropsy (Table 7).

The results of hematology evaluation (Table 8) indicated that pregnant rabbits administered 250 mg PDC/kg/day were anemic, with red blood cell counts, hemoglobin concentration and hematocrit all statistically decreased approximately 23% from control values. Rabbits receiving 100 mg PDC/kg/day exhibited decreases of about 15% in these parameters, although these differences were not statistically identified. Reticulocyte numbers were significantly increased at both the 100 and 250 mg/kg/day dose levels. There

were no effects upon erythrocyte indices noted. Microscopic examination of blood smears (Table 9) demonstrated red blood cell morphologic alterations consistent with a regenerative anemia at 100 and 250 mg/kg/day. These effects consisted of slight to moderate polychromasia, slight to marked anisocytosis and slight to moderate poikilocytosis.

Reproductive Parameters

A summary of the reproductive parameters measured in the surviving rabbits is presented in Table 10. There were no statistically significant differences noted in any of the parameters measured, although there appeared to be a higher resorption rate among rabbits given 250 mg/kg/day when compared to controls, probably secondary to the severe maternal toxicity observed at this dose level. It should be noted that the apparent increase in resorption rate was due in large part to the inclusion of two totally resorbed litters found in rabbits which exhibited a weight loss over the dosing period (Appendix Table 2). In addition, animals in the 250 mg/kg/day dose group exhibited severe anemia when compared to control animals of comparable pregnancy status (Appendix Table 5). It should also be noted that the resorption rate among control rabbits in this study was low relative to historical control data (Table 11)³, and that the resorption rates among animals given 25 or 100 mg PDC/kg/day were well within the historical control range.

SUMMARY AND CONCLUSION

Administration of PDC to pregnant New Zealand White rabbits produced severe maternal toxicity at the 250 mg/kg/day dose level, as evidenced by an increase in mortality consistent with that observed in a previous range-finding study. Maternal toxicity was also evident in the form of treatment-related anemia at 100 or 250 mg/kg/day. Dose-related decreases in hematocrit, hemoglobin concentration, and red blood cell count, as well as increases in

³ Historical control data is listed on an individual study basis in appendix, pp. 44-50.

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reticulocyte count and morphologic changes in red blood cells consistent with regeneration were observed at both dose levels. A possible increase in resorption rate at the 250 mg/kg/day dose level was noted; however, this was considered secondary to the severe maternal toxicity observed at this dose level. Based on these results, dose levels of 0, 15, 50, or 150 mg/kg/day were selected for the definitive teratology study.

SIGNATURES

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TABLE 1

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW ZEALAND WHITE RABBITS

SUMMARY OF DOSE SOLUTION CONCENTRATIONS

DOSE LEVEL ^a	ANALYTICAL CONCENTRATION ^{b, c}	% OF TARGETED CONCENTRATION
0	N.D. ^d	---
25	$(2.37 \pm 0.15) \times 10^1$	95
100	$(9.75 \pm 0.08) \times 10^1$	98
250	$(2.40 \pm 0.03) \times 10^2$	96

^a TARGETED CONCENTRATION, MG/KG/DAY (MG/ML)

^b MG/ML

^c MEAN \pm S.D.

^d NOT DETECTED AT A DETECTION LIMIT OF 2.4×10^{-1} mg/ml

TABLE 2

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW ZEALAND WHITE RABBITS
SUMMARY OF IN-LIFE OBSERVATIONS

	DOSE LEVELS (MG/KG/DAY)			
	0	25	100	250
NUMBER EXAMINED	7	7	7	7
	<u>NUMBER AFFECTED</u>			
NORMAL	7	7	7	5
DEAD	0	0	0	2

TABLE 3

PROPYLENE DICHLORIDE: CRAL TERATOLOGY PROBE STUDY
IN NEW ZEALAND WHITE RABBITS

BODY WEIGHTS (KG) OF PREGNANT FEMALES

DOSE MG/KG/DAY		DAY OF GESTATION						
		0	7	10	13	16	19	20
0	MEAN	3.68	3.86	3.89	3.86	3.85	3.72	3.72
	S.D.	0.31	0.35	0.38	0.29	0.31	0.35	0.36
	N=	4	4	4	4	4	4	4
25	MEAN	3.44	3.60	3.67	3.73	3.78	3.75	3.76
	S.D.	0.29	0.32	0.29	0.28	0.20	0.25	0.26
	N=	3	3	3	3	3	3	3
100	MEAN	3.89	3.99	4.05	4.04	4.04	3.95	3.95
	S.D.	0.34	0.41	0.43	0.38	0.36	0.32	0.33
	N=	5	5	5	5	5	5	5
250	MEAN	3.69	3.87	3.85	3.83	3.94	4.18	4.21
	S.D.	0.38	0.37	0.47	0.58	0.57	0.18	0.15
	N=	5	5	5	5	4	3	3

THERE WERE NO STATISTICALLY IDENTIFIED DIFFERENCES FROM CONTROL MEAN.

TABLE 4

PROPYLENE DICHLOPIDE: ORAL TERATOLOGY PROBE STUDY
IN NEW ZEALAND WHITE RABBITS

BODY WEIGHT GAINS (KG) OF PREGNANT FEMALES

DOSE MG/KG/DAY		DAYS OF GESTATION						
		0-7	7-10	10-13	13-16	16-20	7-20	0-20
0	MEAN	0.19	0.02	-0.02	-0.02	-0.13	-0.15	0.04
	S.D.	0.10	0.03	0.11	0.11	0.08	0.23	0.25
	N=	4	4	4	4	4	4	4
25	MEAN	0.16	0.07	0.06	0.05	-0.02	0.16	0.32
	S.D.	0.17	0.03	0.04	0.09	0.07	0.08	0.11
	N=	3	3	3	3	3	3	3
100	MEAN	0.11	0.06	-0.01	0.01	-0.09	-0.04	0.06
	S.D.	0.10	0.04	0.06	0.13	0.11	0.25	0.21
	N=	5	5	5	5	5	5	5
250	MEAN	0.18	-0.02	-0.01	-0.08	0.00	0.09	0.27
	S.D.	0.07	0.14	0.15	0.11	0.09	0.07	0.10
	N=	5	5	5	4	3	3	3

THERE WERE NO STATISTICALLY IDENTIFIED DIFFERENCES FROM CONTROL MEAN.

TABLE 5

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW
ZEALAND WHITE RABBITS

ORGAN WEIGHTS OF PREGNANT RABBITS

DOSE MG/KG/DAY		FINAL BODY WT. (G)	KIDNEYS		LIVER		SPLEEN	
			(G)	(G/100)	(G)	(G/100)	(G)	(G/100)
0	MEAN	3715	16.460	0.443	81.437	2.184	1.647	0.045
	S.D.	357	2.007	0.022	15.460	0.270	0.334	0.012
	N=	4	4	4	4	4	4	4
25	MEAN	3754	16.746	0.445	118.507	3.131	1.762	0.048
	S.D.	258	1.841	0.018	30.291	0.604	0.982	0.030
	N=	3	3	3	3	3	3	3
100	MEAN	3942	19.698	0.500	106.357	2.677	1.832	0.047
	S.D.	326	2.726	0.055	32.783	0.648	0.330	0.012
	N=	5	5	5	5	5	5	5
250	MEAN	4185	21.005	0.502	136.112	3.275	2.551	0.061
	S.D.	161	2.564	0.054	35.007	0.970	0.972	0.022
	N=	3	3	3	3	3	3	3

THERE WERE NO STATISTICALLY IDENTIFIED DIFFERENCES FROM CONTROL MEAN.

TABLE 6

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW
ZEALAND WHITE RABBITS

GROSS PATHOLOGIC OBSERVATIONS@ - SPONTANEOUS DEATHS

SEX	DOSE IN MG/KG/DAY	NUMBER OF RABBITS EXAMINED	FEMALES			
			0	25	100	250
			0	0	0	2
<u>APPENDIX</u>						
WITHIN NORMAL LIMITS.			-	-	-	1
HEMORRHAGE, WALL, FOCAL:	- SLIGHT		-	-	-	1
<u>DIGESTIVE TRACT</u>						
WITHIN NORMAL LIMITS.			-	-	-	1
DECREASED INGESTA:			-	-	-	1
<u>EXTERNAL AND SKIN</u>						
WITHIN NORMAL LIMITS.			-	-	-	1
PERINEAL SOILING:			-	-	-	1
<u>GALLBLADDER</u>						
WITHIN NORMAL LIMITS.			-	-	-	1
DISTENDED:			-	-	-	1
<u>KIDNEYS</u>						
WITHIN NORMAL LIMITS.			-	-	-	1
PALE:			-	-	-	1
<u>LIVER</u>						
WITHIN NORMAL LIMITS.			-	-	-	1
PALE:			-	-	-	1

TABLE 6 (CONTINUED)

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW
 ZEALAND WHITE RABBITS

GROSS PATHOLOGIC OBSERVATIONS^a - SPONTANEOUS DEATHS

<u>SEX</u> <u>DOSE IN MG/KG/DAY</u> <u>NUMBER OF RABBITS EXAMINED</u>	<u>FEMALES</u>			
	<u>0</u>	<u>25</u>	<u>100</u>	<u>250</u>
	0	0	0	2
<u>LUNGS</u>				
WITHIN NORMAL LIMITS.	-	-	-	0
CONGESTION, GENERALIZED:	-	-	-	2
EDEMA, GENERALIZED:	-	-	-	2
<u>STOMACH</u>				
WITHIN NORMAL LIMITS.	-	-	-	0
EROSION(S) AND/OR ULCER(S):	-	-	-	2
<u>UTERUS</u>				
WITHIN NORMAL LIMITS.	-	-	-	0
PREGNANT:	-	-	-	2
<u>ALL OTHER TISSUES (COMPLETE NECROPSY PERFORMED)</u>				
WITHIN NORMAL LIMITS.	-	-	-	2

^a DATA ARE THE NUMBER OF ANIMALS WITH THE SPECIFIED OBSERVATION.
 - INDICATES NOT APPLICABLE.

TABLE 7

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW
ZEALAND WHITE RABBITS

GROSS PATHOLOGIC OBSERVATIONS⁰ - TERMINAL SACRIFICE

<u>SEX</u>	<u>FEMALES</u>			
	<u>0</u>	<u>25</u>	<u>100</u>	<u>250</u>
<u>DOSE IN MG/KG/DAY</u>				
<u>NUMBER OF RABBITS EXAMINED</u>	<u>7</u>	<u>7</u>	<u>7</u>	<u>5</u>
<u>LIVER</u>				
WITHIN NORMAL LIMITS.	4	7	4	3
PALE:	3	0	3	2
<u>OVIDUCTS</u>				
WITHIN NORMAL LIMITS.	4	4	6	4
CYST - CLEAR:	0	1	1	0
CYST - CLEAR. FOCAL:	1	1	0	1
CYST - CLEAR, MULTIFOCAL:	2	1	0	0
<u>UTERUS</u>				
WITHIN NORMAL LIMITS.	0	0	0	0
NONPREGNANT:	3	4	2	0
PREGNANT-ALL FETUS(ES) APPEAR NORMAL:	2	0	3	1
PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS AND/OR DEAD FETUS(ES):	2	3	2	2
PREGNANT-ALL FETUS(ES) APPARENTLY RESORBED:	0	0	0	2
<u>ALL OTHER TISSUES (COMPLETE NECROPSY PERFORMED)</u>				
WITHIN NORMAL LIMITS.	7	7	7	5

⁰ DATA ARE THE NUMBER OF ANIMALS WITH THE SPECIFIED OBSERVATION.
- INDICATES NOT APPLICABLE.

TABLE 8

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW
ZEALAND WHITE RABBITS

HEMATOLOGY PARAMETERS OF PREGNANT RABBITS

DOSE MG/KG/DAY		RBC	HGB	HCT	MCV	MCH	MCHC	PLAT	WBC	RETIC
		X10E6 /CU MM	G/DL	%	CUBIC MICRON	MICRO MICGRM	%	X10E3 /CU,MM	X10E3 /CU MM	%
0	MEAN	5.67	12.7	42.6	75.6	22.36	29.76	346	6.4	2.1
	S.D.	0.43	1.1	3.1	1	0.5	0.4	71	1.3	1.2
	N=	4	4	4	4	4	4	4	4	4
25	MEAN	6.01	12.9	44.1	74.6	21.56	29.26	362	6.2	2.5
	S.D.	0.25	0.3	1.7	1	0.4	0.4	56	0.9	0.4
	N=	3	3	3	3	3	3	3	3	3
100	MEAN	4.75	10.8	36.1	76.6	22.86	30.06	278	6.6	4.5*
	S.D.	0.81	1.7	5.8	1	0.8	0.5	134	2.0	1.0
	N=	5	5	5	5	5	5	5	5	5
250	MEAN	4.35*	9.7*	33.4*	77.6	22.26	29.06	329	7.6	7.8*
	S.D.	0.44	1.3	4.2	2	0.9	0.4	282	2.1	1.5
	N=	3	3	3	3	3	3	3	3	3

* STATISTICALLY DIFFERENT FROM CONTROL MEAN BY DUNNETT'S TEST, ALPHA = 0.05.

6 INDICATES NO STATISTICAL COMPARISON OF MEANS.

ANIMALS THAT ARE NONPREGNANT OR THAT HAVE TOTALLY RESORBED LITTERS
ARE EXCLUDED FROM ANALYSIS.

TABLE 9

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW
ZEALAND WHITE RABBITS

DOSE MG/KG/DAY	ANIMAL NUMBER	RBC MORPHOLOGY	
		MORPHOLOGY	
C	88A0848 ^a	NORMAL	
	88A0849 ^a	NORMAL	
	88A0850 ^a	NORMAL	
	88A0851	NORMAL	
	88A0852	NORMAL	
	88A0853	NORMAL	
	88A0854	NORMAL	
25	88A0855	NORMAL	
	88A0856	NORMAL	
	88A0857 ^a	NORMAL	
	88A0858	NORMAL	
	88A0859 ^a	NORMAL	
	88A0860 ^a	NORMAL	
	88A0861 ^a	SLIGHT POLYCHROMASIA	
100	88A0862	SLIGHT POLYCHROMASIA, SLIGHT ANISOCYTOSIS	
	88A0863	NORMAL	
	88A0864	SLIGHT POLYCHROMASIA	
	88A0865 ^a	NORMAL	
	88A0866	SLIGHT POLYCHROMASIA	
	88A0867 ^a	NORMAL	
	88A0868	MODERATE POLYCHROMASIA, MARKED ANISOCYTOSIS, MODERATE POIKILOCYTOSIS	
250	88A0871	MODERATE POLYCHROMASIA, MODERATE ANISOCYTOSIS	
	88A0872	MODERATE POLYCHROMASIA, SLIGHT ANISOCYTOSIS	
	88A0873 ^b	SLIGHT ANISOCYTOSIS, SLIGHT POIKILOCYTOSIS	
	88A0874	MODERATE POLYCHROMASIA, MODERATE ANISOCYTOSIS	
	88A0875 ^b	NORMAL	

^aNON-PREGNANT

^bTOTALLY RESORBED LITTERS

TABLE 10
 PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW ZEALAND WHITE RABBITS
 OBSERVATIONS MADE AT NECROPSY

	DOSE LEVEL (MG/KG/DAY)			
	0	25	100	250
NUMBER BRED	7	7	7	7
NUMBER OF DEATHS	0	0	0	2
NUMBER PREGNANT	4	3	5	7
% PREGNANT ^a	57.1 (4/7)	42.9 (3/7)	71.4 (5/7)	100.0 (7/7)
PREGNANCIES DETECTED				
BY STAIN ^b	0	0	0	0
NUMBER OF LITTERS	4	3	5	3
TOTALLY RESORBED LITTERS	0	0	0	2
CORPORA LUTEA/DOE ^c	14.0 ± 2.2	10.7 ± 2.1	13.2 ± 4.2	12.0 ± 5.7
IMPLANTATIONS/DOE ^c	10.3 ± 3.6	7.3 ± 3.2	10.2 ± 1.8	8.4 ± 5.7
% PRE-IMPLANTATION LOSS ^d	27.1 ± 19.6	32.9 ± 17.3	17.9 ± 21.4	6.3 ± 8.8
FETUSES/LITTER ^c	9.8 ± 3.5	6.3 ± 3.2	8.6 ± 3.8	6.4 ± 6.1
RESORPTIONS/LITTER ^{c,e}	0.5 ± 0.6	1.0 ± 0.0	1.6 ± 2.6	2.0 ± 2.0
% IMPLANTATIONS RESORBED	4.9 (2/41)	13.6 (3/22)	15.7 (8/51)	23.8 (10/42)
% LITTERS WITH RESORPTIONS	50.0 (2/4)	100.0 (3/3)	40.0 (2/5)	80.0 (4/5)
RESORPTIONS/LITTER WITH RESORPTIONS ^e	1.0 (2/2)	1.0 (3/3)	4.0 (8/2)	2.5 (10/4)

a NO. OF FEMALES WITH IMPLANTATION SITES/TOTAL NO. OF FEMALES BRED.

b NO OF FEMALES WITH IMPLANTATION SITES DETECTED AFTER STAINING WITH SODIUM SULFIDE/TOTAL NO. STAINED

c MEAN ± S.D.

d PERCENT PER LITTER, MEAN ± S.D.

e NOT STATISTICALLY ANALYZED.

THERE WERE NO STATISTICALLY IDENTIFIED DIFFERENCES FROM THE CONTROL VALUES, ALPHA = 0.05.

TABLE 11

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW ZEALAND WHITE RABBITS

HISTORICAL CONTROL^a
 OBSERVATIONS MADE AT NECROPSY

	MEAN VALUE	INDIVIDUAL RANGE
NUMBER BRED	6.90	5.0-10.0
NUMBER PREGNANT	5.55	2.0-9.0
% PREGNANT	81.05	28.6-100.0
# MATERNAL DEATHS	0.07	0-1
% MATERNAL DEATHS	0.99	0-14.3
# PREGNANT WITH STAIN	0.04	0-1
# ABORTED	0	0-0
% ABORTED	0	0-0
TOTALLY RESORBED LITTERS	0.24	0-1
# LITTERS	5.46	2-9
CORPORA LUTEA/DOE	10.73	0-13
IMPLANTATIONS/DOE	8.27	5-10.3
% PRE-IMPLANTATION LOSS	22.04	0-44
FETUSES/LITTER	7.49	5-9.6
RESORPTIONS/LITTER	0.75	0-2.2
# IMPLANTATIONS RESORBED	4.21	0-20
% IMPLANTATIONS RESORBED	8.29	0-24
# LITTERS W/RESORPTIONS	2.37	0-6
% LITTERS W/RESORPTIONS	40.76	0-83
RESORPTIONS/LITTERS W/RESORPTIONS	1.64	0-4

^a Data collected from 29 studies conducted from 1978 thru 1988. Routes of exposure include inhalation, oral gavage, and dermal exposure. Data from individual studies are listed in Appendix.

APPENDIX

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN
NEW ZEALAND WHITE RABBITS

INDIVIDUAL ANIMAL DATA

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TABLE 1

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW ZEALAND WHITE RABBITS

INDIVIDUAL IN-LIFE OBSERVATIONS

0 MG/KG/DAY

ANIMAL NUMBER	GESTATION DAY	OBSERVATIONS
88A-0848	0-20	APPEARED NORMAL
88A-0849	0-20	APPEARED NORMAL
88A-0850	0-20	APPEARED NORMAL
88A-0851	0-20	APPEARED NORMAL
88A-0852	0-20	APPEARED NORMAL
88A-0853	0-20	APPEARED NORMAL
88A-0854	0-20	APPEARED NORMAL

25 MG/KG/DAY

ANIMAL NUMBER	GESTATION DAY	OBSERVATIONS
88A-0855	0-20	APPEARED NORMAL
88A-0856	0-20	APPEARED NORMAL
88A-0857	0-20	APPEARED NORMAL
88A-0858	0-20	APPEARED NORMAL
88A-0859	0-20	APPEARED NORMAL
88A-0860	0-20	APPEARED NORMAL
88A-0861	0-20	APPEARED NORMAL

TABLE 1 (CONTINUED)

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW ZEALAND WHITE RABBITS

INDIVIDUAL IN-LIFE OBSERVATIONS

ANIMAL NUMBER	100 MG/KG/DA"		OBSERVATIONS
	GESTATION DAY		
88A-0862	0-20		APPEARED NORMAL
88A-0863	0-20		APPEARED NORMAL
88A-0864	0-20		APPEARED NORMAL
88A-0865	0-20		APPEARED NORMAL
88A-0866	0-20		APPEARED NORMAL
88A-0867	0-20		APPEARED NORMAL
88A-0868	0-20		APPEARED NORMAL
250 MG/KG/DAY			
ANIMAL NUMBER	GESTATION DAY		OBSERVATIONS
88A-0869	0-17		APPEARED NORMAL
	18		DEAD
88A-0870	0-14		APPEARED NORMAL
	15		DEAD
88A-0871	0-20		APPEARED NORMAL
88A-0872	0-20		APPEARED NORMAL
88A-0873	0-20		APPEARRED NORMAL
88A-0874	0-20		APPEARED NORMAL
88A-0875	0-20		APPEARED NORMAL

TABLE 2

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY
IN NEW ZEALAND WHITE RABBITS

INDIVIDUAL DATA: BODY WEIGHTS (KG)

DOSE MG/KG/DAY	ANIMAL NUMBER	DAY OF GESTATION						
		0	7	10	13	16	19	20
0	88A0848	3.660	3.760	3.790	3.800	3.810	3.730	3.700
	88A0849	4.250	4.550	4.620	4.670	4.770	4.590	4.630
	88A0850	4.170	4.370	4.420	4.310	4.370	4.330	4.360
	88A0851	3.39	3.46	3.46	3.50	3.43	3.24	3.21
	88A0852	3.69	3.85	3.86	3.93	4.07	4.04	4.02
	88A0853	4.10	4.31	4.38	4.20	4.11	3.91	3.94
	88A0854	3.52	3.83	3.84	3.82	3.78	3.69	3.69
	MEAN	3.68	3.86	3.89	3.86	3.85	3.72	3.72
	S.D.	0.31	0.35	0.38	0.29	0.31	0.35	0.36
	N=	4	4	4	4	4	4	4
25	88A0855	3.68	3.96	4.00	4.05	4.00	4.02	4.04
	88A0856	3.12	3.36	3.44	3.55	3.62	3.54	3.53
	88A0857	3.950	4.170	4.240	4.260	4.340	4.340	4.340
	88A0858	3.51	3.48	3.57	3.60	3.72	3.68	3.71
	88A0859	4.330	4.450	4.540	4.600	4.670	4.630	4.680
	88A0860	4.070	4.270	4.370	4.380	4.380	4.310	4.370
	88A0861	4.130	4.290	4.380	4.240	4.300	4.250	4.280
	MEAN	3.44	3.60	3.67	3.73	3.78	3.75	3.76
	S.D.	0.29	0.32	0.29	0.28	0.20	0.25	0.26
	N=	3	3	3	3	3	3	3

TABLE 2 (CONTINUED)

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY
IN NEW ZEALAND WHITE RABBITS

INDIVIDUAL DATA: BODY WEIGHTS (KG)

DOSE MG/KG/DAY	ANIMAL NUMBER	DAY OF GESTATION						
		0	7	10	13	16	19	20
100	88A0862	4.14	4.18	4.20	4.20	4.20	4.05	4.01
	88A0863	3.97	4.09	4.18	4.20	4.32	4.31	4.36
	88A0864	3.43	3.46	3.47	3.50	3.64	3.60	3.59
	88A0865	3.980	4.070	4.200	4.200	4.200	4.200	4.270
	88A0866	3.65	3.72	3.80	3.82	3.67	3.63	3.63
	88A0867	3.370	3.400	3.430	3.400	3.550	3.550	3.560
	88A0868	4.24	4.51	4.59	4.47	4.33	4.14	4.26
	MEAN	3.89	3.99	4.05	4.04	4.04	3.95	3.95
	S.D.	0.34	0.41	0.43	0.36	0.36	0.32	0.33
	N=	5	5	5	5	5	5	5
250	88A0869	3.24	3.45	3.38	3.32	3.13	***	***
	88A0870	3.40	3.52	3.35	3.12	***	***	***
	88A0871	4.03	4.23	4.41	4.41	4.31	4.19	4.24
	88A0872	4.12	4.21	4.12	4.30	4.37	4.35	4.34
	88A0873	4.210	4.410	4.420	4.430	4.350	4.200	4.150
	88A0874	3.65	3.92	3.97	4.01	3.93	3.99	4.04
	88A0875	3.770	3.870	3.830	3.730	3.760	3.770	3.770
	MEAN	3.60	3.87	3.85	3.83	3.94	4.18	4.21
	S.D.	0.38	0.37	0.47	0.58	0.57	0.18	0.15
	N=	5	5	5	5	4	3	3

*** DEAD ANIMAL.

0 VALUES EXCLUDED FROM ANALYSIS.

ANIMALS THAT ARE NOT PREGNANT OR HAVE TOTALLY RESORBED LITTERS ARE
EXCLUDED FROM ANALYSIS.

TABLE 3

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY
IN NEW ZEALAND WHITE RABBITS

INDIVIDUAL DATA: BODY WEIGHT GAINS (KG)

DOSE MG/KG/DAY	ANIMAL NUMBER	DAYS OF GESTATION						
		0-7	7-10	10-13	13-16	16-20	7-20	0-20
0	88A0848	0.100	0.030	0.010	0.010	-0.110	-0.060	0.040
	88A0849	0.300	0.070	0.050	0.100	-0.140	0.080	0.300
	88A0850	0.200	0.050	-0.110	0.060	-0.010	-0.010	0.190
	88A0851	0.07	0.00	0.04	-0.07	-0.22	-0.25	-0.18
	88A0852	0.16	0.01	0.07	0.14	-0.05	0.17	0.33
	88A0853	0.21	0.07	-0.18	-0.09	-0.17	-0.37	-0.16
	88A0854	0.31	0.01	-0.02	-0.04	-0.09	-0.14	0.17
	MEAN	0.19	0.02	-0.02	-0.02	-0.13	-0.15	0.04
	S.D.	0.10	0.03	0.11	0.11	0.08	0.23	0.25
	N=	4	4	4	4	4	4	4
25	88A0855	0.28	0.04	0.05	-0.05	0.04	0.08	0.36
	88A0856	0.24	0.08	0.11	0.07	-0.09	0.17	0.41
	88A0857	0.220	0.070	0.020	0.080	0.000	0.170	0.390
	88A0858	-0.03	0.09	0.03	0.12	-0.01	0.23	0.20
	88A0859	0.120	0.090	0.060	0.070	0.010	0.230	0.350
	88A0860	0.200	0.100	0.010	0.000	-0.010	0.100	0.300
	88A0861	0.160	0.090	-0.140	0.060	-0.020	-0.010	0.150
	MEAN	0.16	0.07	0.06	0.05	-0.02	0.16	0.32
	S.D.	0.17	0.03	0.04	0.09	0.07	0.08	0.11
	N=	3	3	3	3	3	3	3

TABLE 3 (CONTINUED)

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY
IN NEW ZEALAND WHITE RABBITS

INDIVIDUAL DATA: BODY WEIGHT GAINS (KG)

DOSE MG/KG/DAY	ANIMAL NUMBER	DAYS OF GESTATION						
		0-7	7-10	10-13	13-16	16-20	7-20	0-20
100	88A0862	0.04	0.02	0.00	0.00	-0.19	-0.17	-0.13
	88A0863	0.12	0.09	0.02	0.12	0.04	0.27	0.39
	88A0864	0.03	0.01	0.03	0.14	-0.05	0.13	0.16
	88A0865	0.090	0.130	0.000	0.080	-0.010	0.200	0.290
	88A0866	0.07	0.08	0.02	-0.15	-0.04	-0.09	-0.02
	88A0867	0.060	0.000	0.050	0.070	0.010	0.130	0.190
	88A0868	0.27	0.08	-0.120	-0.08	-0.23	-0.35	-0.08
	MEAN	0.11	0.06	-0.01	0.01	-0.09	-0.04	0.06
	S.D.	0.10	0.04	0.06	0.13	0.11	0.25	0.21
	N=	5	5	5	5	5	5	5
250	88A0869	0.21	-0.07	-0.06	-0.19	***	***	***
	88A0870	0.12	-0.17	-0.23	***	***	***	***
	88A0871	0.27	0.18	0.00	-0.10	-0.07	0.01	0.21
	88A0872	0.09	-0.09	0.18	0.07	-0.03	0.13	0.22
	88A0873	0.200	0.010	0.010	-0.080	-0.200	-0.260	-0.060
	88A0874	0.27	0.05	0.04	-0.08	0.11	0.12	0.39
	88A0875	0.100	-0.040	-0.100	0.030	0.010	-0.100	0.000
	MEAN	0.19	-0.02	-0.01	-0.08	0.00	0.09	0.27
	S.D.	0.07	0.14	0.15	0.11	0.09	0.07	0.10
	N=	5	5	5	4	3	3	3

*** DEAD ANIMAL.

0 VALUES EXCLUDED FROM ANALYSIS.

STATISTICAL OUTLIERS INCLUDED IN ANALYSIS.

ANIMALS THAT ARE NOT PREGNANT OR HAVE TOTALLY RESORBED LITTERS ARE EXCLUDED FROM ANALYSIS.

TABLE 4

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW
ZEALAND WHITE RABBITS

INDIVIDUAL DATA: ORGAN WEIGHTS

DOSE MG/KG/DAY	ANIMAL NUMBER	FINAL BODY WT. (G)	KIDNEYS		LIVER		SPLEEN	
			(G)	(G/100)	(G)	(G/100)	(G)	(G/100)
0	88A0848	3696	16.930	0.458	107.960	2.921	1.248	0.034
	88A0849	4628	19.158	0.414	124.211	2.684	3.094	0.067
	88A0850	4349	19.535	0.449	93.978	2.161	1.611	0.037
	88A0851	3210	14.241	0.444	67.172	2.093	1.926	0.060
	88A0852	3980	18.067	0.454	102.858	2.584	1.184	0.030
	88A0853	3953	18.248	0.462	81.674	2.066	1.852	0.047
	88A0854	3717	15.285	0.411	74.043	1.992	1.627	0.044
	MEAN	3715	16.460	0.443	81.437	2.184	1.647	0.045
	S.D.	357	2.207	0.022	15.460	0.270	0.334	0.012
	N=	4	4	4	4	4	4	4
25	88A0855	4036	18.782	0.455	147.710	3.660	1.049	0.026
	88A0856	3528	15.199	0.431	87.235	2.473	2.882	0.082
	88A0857	4336	18.047	0.416	121.799	2.809	2.808	0.065
	88A0858	3619	16.258	0.440	120.575	3.260	1.355	0.037
	88A0859	4685	21.834	0.466	122.326	2.610	1.707	0.036
	88A0860	4371	18.630	0.426	96.421	2.205	2.727	0.062
	88A0861	4297	17.787	0.402	94.298	2.195	2.302	0.054
	MEAN	3754	16.746	0.445	118.507	3.131	1.762	0.048
	S.D.	258	1.841	0.018	30.291	0.604	0.982	0.030
	N=	3	3	3	3	3	3	3

TABLE 4 (CONTINUED)

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW
ZEALAND WHITE RABBITS

INDIVIDUAL DATA: ORGAN WEIGHTS

DOSE MG/KG/DAY	ANIMAL NUMBER	FINAL BODY WT. (G)	KIDNEYS		LIVER		SPLEEN	
			(G)	(G/100)	(G)	(G/100)	(G)	(G/100)
100	88A0852	4005	17.290	0.432	85.912	2.145	1.621	0.040
	88A0863	4344	20.502	0.472	163.993#	3.775	1.521	0.035
	88A0864	3582	17.189	0.499	85.969	2.400	2.069	0.058
	88A0865	4241@	19.869@	0.468@	127.037@	2.995@	1.511@	0.036@
	88A0866	3638	18.740	0.515	99.024	2.722	2.289	0.063
	88A0867	3528@	17.953@	0.509@	92.637@	2.626@	1.347@	0.038@
	88A0868	4139	24.068	0.581	96.888	2.341	1.658	0.040
	MEAN	3942	19.698	0.500	135.7	2.677	1.832	0.047
	S.D.	326	2.726	0.055	32.783	0.648	0.330	0.012
	N=	5	5	5	5	5	5	5
250	88A0869	***	***	***	***	***	***	***
	88A0870	***	***	***	***	***	***	***
	88A0871	1219	23.806	0.564	110.407	2.617	1.632	0.039
	88A0872	4327	20.496	0.474	121.947	2.818	3.568	0.082
	88A0873	4051@	17.791@	0.439@	95.758@	2.364@	1.280@	0.032@
	88A0874	4010	18.714	0.467	175.982	4.389	2.451	0.061
	88A0875	3760@	16.983@	0.452@	107.498@	2.859@	1.999@	0.053@
	MEAN	4185	21.005	0.502	136.112	3.275	2.551	0.061
	S.D.	161	2.584	0.054	35.007	0.970	0.972	0.022
	N=	3	3	3	3	3	3	3

*** DEAD ANIMAL.

@ VALUES EXCLUDED FROM ANALYSIS.

STATISTICAL OUTLIERS INCLUDED IN ANALYSIS.

ANIMALS THAT ARE NONPREGNANT OR HAVE TOTALLY RESORBED LITTERS ARE EXCLUDED FROM ANALYSIS.

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW ZEALAND WHITE RABBITS

[illegible]

TABLE 5 (CONTINUED)

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY IN NEW
ZEALAND WHITE RABBITS

INDIVIDUAL DATA: HEMATOLOGY

DOSE MG/KG/DAY	ANIMAL NUMBER	RBC X10E6 /CU MM	HGB G/DL	HCT %	MCV CUBIC MICRON	MCH MICRO MICGRM	MCHC %	PLA' X10E3 /CU MM	WBC X10E3 /CU MM	RETIC %
100	88A0862	4.73	10.7	35.9	76	22.6	29.8	389	5.8	4.0
	88A0863	5.38	11.7	39.8	74	21.7	29.4	59	4.1	3.6
	88A0864	4.80	11.4	37.1	77	23.8	30.7	258	6.6	4.2
	88A0865	5.93@	12.9@	43.7@	74@	21.8@	29.5@	361@	7.5@	1.2@
	88A0866	5.43	12.4	41.3	76	22.8	30.0	300	7.1	4.4
	88A0867	5.85@	12.5@	42.7@	73@	21.4@	29.3@	350@	9.9@	2.5@
	88A0868	3.43	8.0	26.5	77	23.3	30.2	382	9.6	6.2
	MEAN	4.75	10.8	36.1	76	22.8	30.0	278	6.6	4.5
	S.D.	0.81	1.7	5.8	1	0.8	0.5	134	2.0	1.0
	N=	5	5	5	5	5	5	5	5	5
250	88A0869	***	***	***	***	***	***	***	***	***
	88A0870	***	***	***	***	***	***	***	***	***
	88A0871	3.86	8.2	28.7	74	21.2	28.6	62	5.7	9.2
	88A0872	4.71	10.8	36.8	78	22.9	29.3	301	7.1	8.0
	88A0873	5.04@	11.3@	38.0@	75@	22.4@	29.7@	529@	6.6@	3.9@
	88A0874	4.47	10.1	34.8	78	22.6	29.0	624	9.9	6.2
	88A0875	4.79@	10.1@	34.5@	72@	21.1@	29.3@	458@	8.7@	3.2@
	MEAN	4.35	9.7	33.4	77	22.2	29.0	329	7.6	7.8
	S.D.	0.44	1.3	4.2	2	0.9	0.4	282	2.1	1.5
	N=	3	3	3	3	3	3	3	3	3

*** DEAD ANIMAL.

@ VALUES EXCLUDED FROM ANALYSIS.

TABLE 6

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY
 IN NEW ZEALAND WHITE RABBITS

INDIVIDUAL DATA: OBSERVATIONS MADE AT TIME OF NECROPSY

DOSE MG/KG/DAY	ANIMAL NUMBER	CORPORA LUTEA	IMPLAN- TATIONS	PRE-IMP LOSS	RE-SORP- TIONS	LITTER SIZE
0	88A0848	---	---	---	---	---
	88A0849	---	---	---	---	---
	88A0850	---	---	---	---	---
	88A0851	15.0	7.0	8.0	1.0	6.0
	88A0852	11.0	8.0	3.0	0.0	8.0
	88A0853	16.0	15.0	1.0	1.0	14.0
	88A0854	14.0	11.0	3.0	0.0	11.0
	MEAN	14.0	10.7	3.8	0.5	9.8
	S.D.	2.2	3.6	3.0	0.6	3.5
	N=	4	4	4	4	4
25	88A0855	9.0	6.0	3.0	1.0	5.0
	88A0856	13.0	11.0	2.0	1.0	10.0
	88A0857	---	---	---	---	---
	88A0858	10.0	5.0	5.0	1.0	4.0
	88A0859	---	---	---	---	---
	88A0860	---	---	---	---	---
	88A0861	---	---	---	---	---
	MEAN	10.7	7.3	3.3	1.0	6.3
	S.D.	2.1	3.2	1.5	0.0	3.2
	N=	3	3	3	3	3

TABLE 6 (CONTINUED)

PROPYLENE DICHLORIDE: ORAL TERATOLOGY PROBE STUDY
IN NEW ZEALAND WHITE RABBITS

INDIVIDUAL DATA: OBSERVATIONS MADE AT TIME OF NECROPSY

DOSE MG/KG/DAY	ANIMAL NUMBER	CORPORA LUTEA	IMPLAN- TATIONS	PRE-IMP LOSS	RESORP- TIONS	LITTER SIZE
100	88A0862	11.0	10.0	1.0	0.0	10.0
	88A0863	9.0	8.0	1.0	6.0	2.0
	88A0864	14.0	12.0	2.0	2.0	10.0
	88A0865	---	---	---	---	---
	88A0866	20.0	9.0	11.0#	0.0	9.0
	88A0867	---	---	---	---	---
	88A0868	12.0	12.0	0.0	0.0	12.0
	MEAN	13.2	10.2	3.0	1.6	8.6
	S.D.	4.2	1.8	4.5	2.6	3.8
	N=	5	5	5	5	5
250	88A0869	***	***	***	***	***
	89A0870	***	***	***	***	***
	88A0871	---	14.0	---	1.0	13.0
	88A0872	16.0	14.0	2.0	3.0	11.0
	88A0873	---	5.0	---	5.0	0.0
	88A0874	8.0	8.0	0.0	0.0	8.0
	88A0875	---	1.0	---	1.0	0.0
	MEAN	12.0	8.4	1.0	2.0	6.4
	S.D.	5.7	5.7	1.4	2.0	6.1
	N=	2	5	2	5	5

--- NO DATA.

*** DEAD ANIMAL.

STATISTICAL OUTLIERS INCLUDED IN ANALYSIS.

HISTORICAL CONTROL DATA
 REPRODUCTIVE INDICES
 PROBE STUDIES
 NZW RABBITS

STUDY #	1	2	3	4	5
DATE	SEPT 78	SEPT 78	SEPT 78	AUG 80	NOV 80
ROUTE	INHAL	INHAL	INHAL	INHAL	INHAL
# BRED	5	5	5	5	7
# PREGNANT	5	5	3	4	7
% PREGNANT	100.00	100.00	60.00	80.00	100.00
# MATERNAL DEATHS	0	0		0	0
% MATERNAL DEATHS	0.00	0.00	0.00	0.00	0.00
# PREGNANT WITH STAIN				1	0
# ABORTED					0
% ABORTED	0.00	0.00	0.00	0.00	0.00
TOTALLY RESORBED LITTERS					0
# LITTERS	5	5	3	3	7
CORPORA LUTEA/DAM				10.3	11
IMPLANTATION SITES/DAM	9	9	5	8.7	9
% PREIMPLANTATION LOSS					16
FETUSES/LITTER	9	8	5		9
RESORPTIONS/LITTER				0	0.1
# IMPLANTATIONS RESORBED	1	2	0	0	1
% IMPLANTATIONS RESORBED	2	5	0	0	2
# LITTERS W/RESORPTIONS				0	1
% LITTERS W/RESORPTIONS				0	14
RESORPTIONS/LITTERS					1.00

HISTORICAL CONTROL DATA
 REPRODUCTIVE INDICES
 PROBE STUDIES
 NZW RABBITS

STUDY #	6	7	8	9	10
DATE	JAN 81	JUN 81	SEPT 82	JAN 82	AUG 82
ROUTE	INHAL	INHAL	INHAL	INHAL	INHAL
# BRED	7	7	7	7	6
# PREGNANT	4	7	6	5	5
% PREGNANT	57.14	100.00	85.71	71.43	83.33
# MATERNAL DEATHS	0	0	0	0	0
% MATERNAL DEATHS	0.00	0.00	0.00	0.00	0.00
# PREGNANT WITH STAIN	0	0	0	0	0
# ABORTED	0	0	0	0	0
% ABORTED	0.00	0.00	0.00	0.00	0.00
TOTALLY RESORBED LITTERS	0	0	1	1	0
# LITTERS	4	7	6	5	5
CORPORA LUTEA/DAM	10	13	12	13	12
IMPLANTATION SITES/DAM	8	9	7	9	9
% PREIMPLANTATION LOSS	24	20	37	12	26
FETUSES/LITTER	7	8	6	7	8
RESORPTIONS/LITTER	1	1.6	1	1.4	1.4
# IMPLANTATIONS RESORBED	4	11	6	7	7
% IMPLANTATIONS RESORBED	13	17	14	16	15
# LITTERS W/RESORPTIONS	2	5	5	4	3
% LITTERS W/RESORPTIONS	50	71	83	80	60
RESORPTIONS/LITTERS	2.00	2.20	1.20	1.75	2.33

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HISTORICAL CONTROL DATA
REPRODUCTIVE INDICES
PROBE STUDIES
NZW RABBITS

STUDY #	11	12	13	14	15
DATE	MAR 83	SEPT 78	MAY 80	SEPT 82	AUG 83
ROUTE	INHAL	ORAL	ORAL	ORAL	ORAL
# BRED	7	5	7	7	7
# PREGNANT	6	5	7	6	5
% PREGNANT	85.71	100.00	100.00	85.71	71.43
# MATERNAL DEATHS	0	0	1	0	0
% MATERNAL DEATHS	0.00	0.00	14.29	0.00	0.00
# PREGNANT WITH STAIN	0	0	0	0	0
# ABORTED	0	0	0	0	0
% ABORTED	0.00	0.00	0.00	0.00	0.00
TOTALLY RESORBED LITTERS	0		1	0	0
# LITTERS	6		6	6	5
CORPORA LUTEA/DAM	11		10	11	12
IMPLANTATION SITES/DAM	8	9	7	8	7
% PREIMPLANTATION LOSS	31		18	20	44
FETUSES/LITTER	7	9	7	8	7
RESORPTIONS/LITTER	0.8		0.17	0.2	0.2
# IMPLANTATIONS RESORBED	5	0	1	1	1
% IMPLANTATIONS RESORBED	11	0	2	2	3
# LITTERS W/RESORPTIONS	3	0	1	1	1
% LITTERS W/RESORPTIONS	50	0	17	17	20
RESORPTIONS/LITTERS	1.67		1.00	1.00	1.00

HISTORICAL CONTROL DATA
 REPRODUCTIVE INDICES
 PROBE STUDIES
 NZW RABBITS

STUDY #	16	17	18	19	20
DATE	AUG 80	DEC 84	DEC 83	MAR 85	JUNE 86
ROUTE	ORAL	DERMAL	DERMAL	ORAL	DERMAL
# BRED	7	10	10	7	10
# PREGNANT	6	9	6	6	7
% PREGNANT	85.71	90.00	60.00	85.71	70.00
# MATERNAL DEATHS	0	0	0	0	0
% MATERNAL DEATHS	0.00	0.00	0.00	0.00	0.00
# PREGNANT WITH STAIN	0	0	0	0	0
# ABORTED	0	0	0	0	0
% ABORTED	0.00	0.00	0.00	0.00	0.00
TOTALLY RESORBED LITTERS		1	0	1	0
# LITTERS		9	6	6	7
CORPORA LUTEA/DAM	12	13	10	11	12
IMPLANTATION SITES/DAM	9	9	9	10	8
% PREIMPLANTATION LOSS	27	28	12	0	30
FETUSES/LITTER	7	7	8	8	7
RESORPTIONS/LITTER	1.8	2.2	0.3	1.3	0.7
# IMPLANTATIONS RESORBED	11	20	2	8	5
% IMPLANTATIONS RESORBED	21	24	4	14	9
# LITTERS W/RESORPTIONS	4	6		5	4
% LITTERS W/RESORPTIONS	67	67	33	83	57
RESORPTIONS/LITTERS	2.75	3.33	1.00	1.60	1.25

HISTORICAL CONTROL DATA
REPRODUCTIVE INDICES
PROBE STUDIES
NZW RABBITS

STUDY #	21	22	23	24	25
DATE	OCT 86	OCT 86	APR 86	APR 86	MAY 86
ROUTE	ORAL	ORAL	ORAL	ORAL	ORAL
# BRED	7	7	7	6	7
# PREGNANT	2	7	4	3	5
% PREGNANT	28.57	100.00	57.14	50.00	71.43
# MATERNAL DEATHS	0	0	0	0	0
% MATERNAL DEATHS	0.00	0.00	0.00	0.00	0.00
# PREGNANT WITH STAIN	0	0	0	0	0
# ABORTED	0	0	0	0	0
% ABORTED	0.00	0.00	0.00	0.00	0.00
TOTALLY RESORBED LITTERS	0	0	0	0	0
# LITTERS	2	7	4	3	5
CORPORA LUTEA/DAM	9.5	12	9	11	11.2
IMPLANTATION SITES/DAM	9	10.3	6.8	6	8.6
% PREIMPLANTATION LOSS	5	13.6	28.8	40	22.3
FETUSES/LITTER	8.5	9.6	6.3	6	8
RESORPTIONS/LITTER	0.5	0.7	0.5	0	0.6
# IMPLANTATIONS RESORBED	1	5	2	0	3
% IMPLANTATIONS RESORBED	5.6	6.9	7.4	0	7
# LITTERS W/RESORPTIONS	1	4	2	0	3
% LITTERS W/RESORPTIONS	50	57.1	50	0	60
RESORPTIONS/LITTERS	1.00	1.25	1.00		1.00

HISTORICAL CONTROL DATA
 REPRODUCTIVE INDICES
 PROBE STUDIES
 NZW RABBITS

STUDY #	26	27	28	29
DATE	DEC 86	DEC 86	MAR 87	APR 88
ROUTE	ORAL	ORAL	ORAL	ORAL
# BRED	7	7	7	7
# PREGNANT	6	7	7	6
% PREGNANT	85.71	100.00	100.00	85.71
# MATERNAL DEATHS	0	0	1	0
% MATERNAL DEATHS	0.00	0.00	14.29	0.00
# PREGNANT WITH STAIN	0	0	0	0
# ABORTED	0	0	0	0
% ABORTED	0.00	0.00	0.00	0.00
TOTALLY RESORBED LITTERS	0	0	0	0
# LITTERS	6	7	6	6
CORPORA LUTEA/DAM	11.2	10.1	11.5	10.3
IMPLANTATION SITES/DAM	8.7	8.9	7.7	7
% PREIMPLANTATION LOSS	20.7	13.6	31.2	30.9
FETUSES/LITTER	8	8.7	7	5.5
RESORPTIONS/LITTER	0.7	0.1	0.7	1.5
# IMPLANTATIONS RESORBED	4	1	4	9
% IMPLANTATIONS RESORBED	7.7	1.6	8.7	21.4
# LITTERS W/RESORPTIONS	2	1	1	3
% LITTERS W/RESORPTIONS	33.3	14.3	16.7	50
RESORPTIONS/LITTERS	2.00	1.00	4.00	3.00

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Irrelevant, Filing Data
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REPRODUCTIVE INDICES
PROBE STUDIES
NZW RABBITS

STUDY # DATE ROUTE	MEAN	RANGE FROM	TO
# BRED	6.90	5.00	10.00
# PREGNANT	5.55	2.00	9.00
% PREGNANT	81.05	28.57	100.00
# MATERNAL DEATHS	0.07	0	1
% MATERNAL DEATHS	0.99	0.00	14.29
# PREGNANT WITH STAIN	0.04	0	1
# ABORTED	0.00	0	0
% ABORTED	0.00	0.00	0.00
TOTALLY RESORBED LITTERS	0.24	0	1
# LITTERS	5.46	2	9
CORPORA LUTEA/DAM	10.73	0	13
IMPLANTATION SITES/DAM	8.27	5	10.3
% PREIMPLANTATION LOSS	22.04	0	44
FETUSES/LITTER	7.49	5	9.6
RESORPTIONS/LITTER	0.75	0	2.2
# IMPLANTATIONS RESORBED	4.21	0	20
% IMPLANTATIONS RESORBED	8.29	0	24
# LITTERS W/RESORPTIONS	2.37	0	6
% LITTERS W/RESORPTIONS	40.76	0	83
RESORPTIONS/LITTERS	1.64	0.00	4.00

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INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 51
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0848

SEX: FEMALE
DOSE: 0

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3696.3

ORGAN WEIGHTS (GRAMS):

LIVER	KIDNEYS	SPLEEN
107.960	16.930	1.248

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

OVIDUCTS

CYST - CLEAR, MULTIFOCAL

UTERUS

NONPREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0848

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 52
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0849

SEX: FEMALE
DOSE: 0

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4628.1

ORGAN WEIGHTS (GRAMS):

LIVER
124.211

KIDNEYS
19.158

SPLEEN
3.094

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

NONPREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0849

THE DOW CHEMICAL COMPAN.

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 53
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0850

SEX: FEMALE
DOSE: 0

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4348.9

ORGAN WEIGHTS (GRAMS):

LIVER
93.978

KIDNEYS
19.535

SPLEEN
1.611

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

OVIDUCTS

CYST - CLEAR, FOCAL

UTERUS

NONPREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0850

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 54
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0851

SEX: FEMALE
DOSE: 0

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3209.0

ORGAN WEIGHTS (GRAMS):

LIVER	KIDNEYS	SPLEEN
67.172	14.241	1.926

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

LIVER

PALE

UTERUS

PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS

AND/OR DEAD FETUS(ES)

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0851

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 55
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0852

SEX: FEMALE
DOSE: 0

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3979.8

ORGAN WEIGHTS (GRAMS):

LIVER	KIDNEYS	SPLEEN
102.858	18.067	1.184

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

PREGNANT-ALL FETUS(ES) APPEAR NORMAL

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0852

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 56
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0853

SEX: FEMALE
DOSE: 0

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3953.4

ORGAN WEIGHTS (GRAMS):

LIVER
81.674

KIDNEYS
18.248

SPLEEN
1.852

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

LIVER

PALE

OVIDUCTS

CYST - CLEAR, MULTIFOCAL

UTERUS

PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS
AND/OR DEAD FETUS(ES)

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0853

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 57
PRINT DATE: 07/15/68

ANIMAL NUMBER: 88A0854

SEX: FEMALE
DOSE: 0

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/68 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3716.5

ORGAN WEIGHTS (GRAMS):

LIVER
74.043

KIDNEYS
15.285

SPLEEN
1.627

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

LIVER

PALE

UTERUS

PREGNANT-ALL FETUS(ES) APPEAR NORMAL

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0854

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE 58
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0855

SEX: FEMALE
DOSE: 25

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4035.6

ORGAN WEIGHTS (GRAMS):

LIVER
147.710

KIDNEYS
18.782

SPLEEN
1.049

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS
AND/OR DEAD FETUS(ES)

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0855

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 59
PRINT DATE: 07/15/86

ANIMAL NUMBER: 88A0856

SEX: FEMALE
DOSE: 25

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3527.6

ORGAN WEIGHTS (GRAMS):

LIVER
87.235

KIDNEYS
15.199

SPLEEN
2.882

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

OVIDUCTS

CYST - CLEAR

UTERUS

PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS
AND/OR DEAD FETUS(ES)

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0856

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 60
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0857

SEX: FEMALE
DOSE: 25

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4336.4

ORGAN WEIGHTS (GRAMS):

LIVER
121.799

KIDNEYS
18.047

SPLEEN
2.808

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

NONPREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0857

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 61
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0858

SEX: FEMALE
DOSE: 25

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3699.4

ORGAN WEIGHTS (GRAMS):

LIVER
120.575

KIDNEYS
16.258

SPLEEN
1.355

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

OVIDUCTS

CYST - CLEAR, FOCAL

UTERUS

PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS
AND/OR DEAD FETUS(ES)

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0858

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 62
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0859 SEX: FEMALE
DOSE: 25

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4686.1

ORGAN WEIGHTS (GRAMS):

LIVER	KIDNEYS	SPLEEN
122.326	21.834	1.707

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

NONPREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0859

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE 63
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0860

SEX: FEMALE
DOSE: 25

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4373.0

ORGAN WEIGHTS (GRAMS):

LIVER
96.421

KIDNEYS
18.630

SPLEEN
2.727

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

NONPREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0860

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 64
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0861

SEX: FEMALE
DOSE: 25

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4296.7

ORGAN WEIGHTS (GRAMS):

LIVER
94.298

KIDNEYS
17.267

SPLEEN
2.302

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

OVIDUCTS

CYST - CLEAR, MULTIFOCAL

UTERUS

NONPREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0861

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 65
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0862

SEX: FEMALE
DOSE: 100

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4004.9

ORGAN WEIGHTS (GRAMS):

LIVER
85.912

KIDNEYS
17.290

SPLEEN
1.621

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

LIVER

PALE

OVIDUCTS

CYST - CLEAR

UTERUS

PREGNANT-ALL FETUS(ES) APPEAR NORMAL

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0862

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 66
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0863

SEX: FEMALE

DOSE: 100

MG/KG/DAY

TEST MATERIAL: PDC

MODE OF DEATH: SACRIFICED

NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY

ROUTE: GAVAGE

SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4344.4

ORGAN WEIGHTS (GRAMS):

LIVER
163.993

KIDNEYS
20.502

SPLEEN
1.521

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS
AND/OR DEAD FETUS(ES)

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0863

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 67
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0864

SEX: FEMALE
DOSE: 100

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3582.2

ORGAN WEIGHTS (GRAMS):

LIVER

85.969

ADIPVS
1.989

SPLEEN
2.069

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS
AND/OR DEAD FETUS(ES)

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0864

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 68
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0865	SEX: FEMALE	EST MATERIAL: PDC	DURATION: 20-DAY
DOSE: 100	MG/KG/DAY	MODE OF DEATH: SACRIFICED	ROUTE: GAVAGE
		NECROPSY DATE: 02/24/88 (DAY 20)	SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4240.9

ORGAN WEIGHTS (GRAMS):

LIVER	KIDNEYS	SPLEEN
127.037	19.369	1.511

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

NONPREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0865

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 69
PRINT DATE: 07/15/88

THE DOW CHEMICAL COMPANY

ANIMAL NUMBER: 88A0866

SEX: FEMALE

DOSE: 100

MG/KG/DAY

TEST MATERIAL: PDC

MODE OF DEATH: SACRIFICED

NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY

ROUTE: GAVAGE

SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3637.6

ORGAN WEIGHTS (GRAMS):

LIVER

99.024

KIDNEYS

18.740

SPLEEN

2.289

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

LIVER

PALE

UTERUS

PREGNANT-ALL FETUS(ES) APPEAR NORMAL

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0866

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 70
PRINT DATE: 07/15/86

ANIMAL NUMBER: BBA0867

SEX: FEMALE
DOSE: 100

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3528.3

ORGAN WEIGHTS (GRAMS):

LIVER

92.637

KIDNEYS

17.953

SPLEEN

1.347

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

NONPREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL BBA0867

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 71
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0868

SEX: FEMALE
DOSE: 1.0

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4138.5

ORGAN WEIGHTS (GRAMS):

LIVER
96.888

KIDNEYS
24.068

SPLEEN
1.658

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

LIVER

PALE

UTERUS

PREGNANT-ALL FETUS(ES) APPEAR NORMAL

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0868

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 72
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0869

SEX: FEMALE

DOSE: 250

MG/KG/DAY

TEST MATERIAL: PDC

MODE OF DEATH: SPONTANEOUS

NECROPSY DATE: 02/22/88 (DAY 18)

DURATION: 20-DAY

ROUTE: GAVAGE

SPECIES: RABBIT

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

DIGESTIVE TRACT

DECREASED INGESTA

EXTERNAL AND SKIN

PERINEAL SOILING

GALLBLADDER

DISTENDED

LUNGS

EDFMA, GENERALIZED

CONGESTION, GENERALIZED

STOMACH

EROSION(S) AND/OR ULCER(S)

COMMENT: A SINGLE DARK FOCUS WAS PRESENT.

UTERUS

PREGNANT

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0869

INDIVIDUAL ANIMAL PATHOLOGY REPORT

THE DOW CHEMICAL COMPANY

PAGE - 73
PRINT DATE: 07/15/88

ANIMAL NUMBER: 89A0870

SEX: FEMALE
DOSE: 250

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SPONTANEOUS
NECROPSY DATE: 02/19/88 (DAY 15)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

APPENDIX

HEMORRHAGE, WALL, FOCAL, SLIGHT

KIDNEYS

PALE

LIVER

PALE

LUNGS

CONGESTION, GENERALIZED

EDEMA, GENERALIZED

STOMACH

EROSION(S) AND/OR ULCER(S)

UTERUS

PREGNANT

GENERAL COMMENT

CAUSE OF DEATH NOT DETERMINED.

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0870

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 74
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0871

SEX: FEMALE
DOSE: 250

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4219.0

ORGAN WEIGHTS (GRAMS):

LIVER
110.407

KIDNEYS
23.806

SPLEEN
1.632

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

LIVER

PALE

OVIDUCTS

CVST - CLEAR, FOCAL

UTERUS

PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS
AND/OR DEAD FETUS(ES)

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0871

INDIVIDUAL ANIMAL PATHOLOGY REPORT

THE DOW CHEMICAL COMPANY

PAGE - 75
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0872	SEX: FEMALE	TEST MATERIAL: PDC	DURATION: 20-DAY
DOSE: 250	MG/KG/DAY	MODE OF DEATH: SACRIFICED	ROUTE: GAVAGE
		NECROPSY DATE: 02/24/88 (DAY 20)	SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4326.7

ORGAN WEIGHTS (GRAMS):

LIVER	KIDNEYS	SPLEEN
121.947	20.496	3.568

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

PREGNANT-NORMAL APPEARING FETUS(ES) WITH RESORPTIONS
AND/OR DEAD FETUS(ES)

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0872

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 76
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0873

SEX: FEMALE
DOSE: 250

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4051.2

ORGAN WEIGHTS (GRAMS):

LIVER
95.758

KIDNEYS
17.791

SPLEEN
1.280

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

LIVER

PALE

UTERUS

PREGNANT-ALL FETUS(ES) APPARENTLY RESORBED

ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0873

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE 77
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0874

SEX: FEMALE
DOSE: 250

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 4010.1

ORGAN WEIGHTS (GRAMS):

LIVER
175.982

KIDNEYS
18.714

SPLEEN
2.453

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED):

UTERUS

PREGNANT-ALL FETUS(ES) APPEAR NORMAL
ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0874

THE DOW CHEMICAL COMPANY

INDIVIDUAL ANIMAL PATHOLOGY REPORT

PAGE - 78
PRINT DATE: 07/15/88

ANIMAL NUMBER: 88A0875

SEX: FEMALE
DOSE: 250

MG/KG/DAY

TEST MATERIAL: PDC
MODE OF DEATH: SACRIFICED
NECROPSY DATE: 02/24/88 (DAY 20)

DURATION: 20-DAY
ROUTE: GAVAGE
SPECIES: RABBIT

FINAL BODY WEIGHT (GRAMS): 3759.6

ORGAN WEIGHTS (GRAMS):

LIVER
107.498

KIDNEYS
16.983

SPLEEN
1.999

GROSS PATHOLOGIC OBSERVATIONS (COMPLETE NECROPSY PERFORMED).

UTERUS

PREGNANT-ALL FETUS(ES) APPARENTLY RESORBED
ALL OTHER TISSUES WERE WITHIN NORMAL LIMITS

END OF REPORT FOR ANIMAL 88A0875

CERTIFICATE OF AUTHENTICITY

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END